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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,230

06/21/2005

David L. Reynolds

12916-82

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04/16/2008

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CANADA

EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

04/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,230	<b>Applicant(s)</b> REYNOLDS, DAVID L.	
	<b>Examiner</b> Phil Wiest	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-24 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-24 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

1. In the reply filed 1/11/08, applicant amended claims 1, 3, and 4, cancelled claims 10 & 25-28, and added new claim 29. Claims 1-9, 11-24, and 29 are currently pending.

### ***Response to Arguments***

Applicant's arguments with respect to the rejection(s) of claim(s) 1 under 35 U.S.C. 102(b) has been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly discovered prior art.

### ***Claim Objections***

1. Claim 1 recites the limitation "the penetrable closure" in line 15 of the claim. There is insufficient antecedent basis for this limitation in the claim because the "penetrable closure" is previously referred to as a "penetrable seal."

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 11, 14, 21, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Genese (US 4,180,070).

4. With respect to Claims 1 and 29, Genese discloses an assembly for transferring fluid between a vessel 42 having a piston 31 and a vial 18 comprising a housing 10 having first and second ends and a bore 45 extending therethrough, the piston being removably connected to the housing. A conduit 23 having first and second apertures is longitudinally slidable within the bore between a retracted position (Figure 1) and an activated position (Figure 2). The device further comprises a vial socket assembly 11 having a vial socket (within aperture 14) for receiving a vial, and a hollow piercing member (at piercing point 24) for piercing the vial, said vial socket assembly moveable longitudinally relative to the housing with the housing. The second end of the conduit is fully capable of being releasably connected to the vial socket assembly. Advancing the vial socket assembly longitudinally toward the housing advances the conduit from the retracted position to the activated position to fluidly connect the vessel and the vial. See Figures 1-3.

5. With respect to Claims 2, 11, 14, and 21 the first end of the conduit has a piercing member and the conduit has an aperture at the tip that extends through the

conduit. The interior of the vial socket is a retaining member. The vessel 42 may be a syringe or a cartridge.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4, 9, 11-13, 21, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (US 5,393,497) in view of Genese.

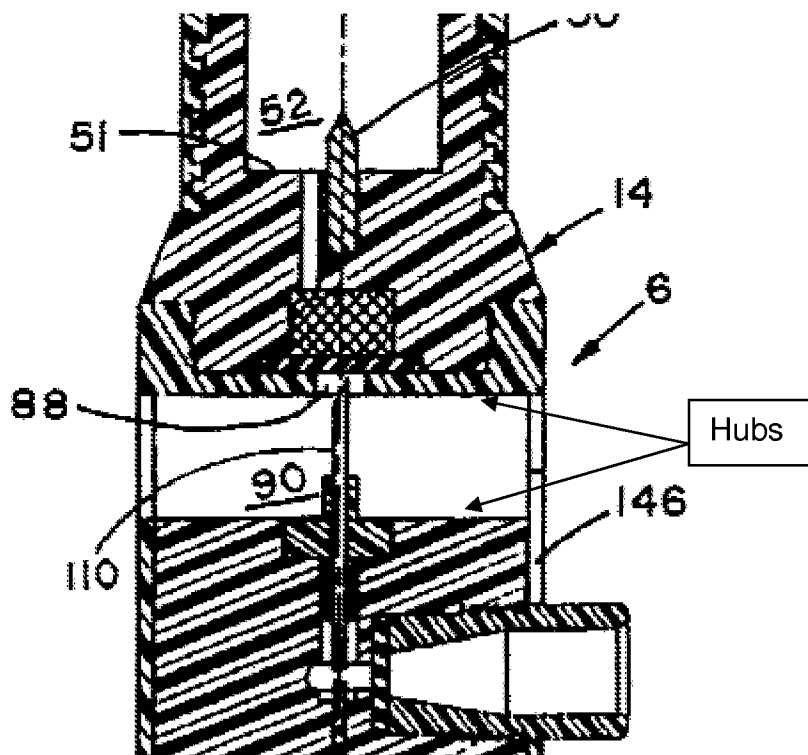
8. With respect to Claims 1 & 29, Haber discloses an assembly for transferring fluid between a vessel and a vial comprising a housing 2 having first and second ends and a bore (22, 90) extending therethrough, and a slidable piston (between spaces 90 and 104 in Figure 3) removably connected to the housing. A conduit (110, 53) having first and second apertures is longitudinally slidable within the bore between a retracted position in which the first aperture (above the piston in figure 3) is positioned within the housing and connected to the piston, and an activated position in which the first aperture protrudes into the body of a vessel 10 that is attached to the housing. The device further comprises a vial socket assembly (48, 58) having a vial socket (48, 58) for receiving a vial, and a hollow piercing member 53 for piercing the vial, said vial socket assembly moveable longitudinally relative to the housing with the housing. The

second end of the conduit is releasably connected to the vial socket assembly.

Advancing the vial socket assembly longitudinally toward the housing advances the conduit from the retracted position to the activated position to fluidly connect the vessel and the vial. Haber, however, does not specifically disclose that the slidable piston is located within the vessel.

Genese discloses a fluid transfer assembly for transferring fluids between a vessel and a vial comprising a vessel 42 having a piston 31 disposed therein. The vessel and piston are capable of moving relative to the assembly, thereby allowing the conduit to puncture the piston and create fluid communication between the vessel and the vial. By locating the piston within the vessel, it creates a seal, thereby preventing fluids from exiting the vessel except through the conduit (see Figures 1-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the transfer device of Haber with the piston enclosed in the vessel of Genese in order to provide a sealing means that allows fluid to be transferred through the conduit when the device is advanced to the second position.

9. With respect to Claims 2 and 3, the first end of the conduit has a piercing member that pierces the vessel, and the aperture is an opening adjacent the tip of the piercing member. A plurality of hubs are also disposed in the housing:



10. With respect to Claim 4, the vial socket assembly comprises a post (36, 37) for receiving the second end of the conduit.

11. With respect to claim 9, Haber discloses an aperture on the sidewall of the conduit having a blunt end.

12. With respect to Claims 11-13, the vial socket assembly (48, 58) comprises a retaining member (30, 60) in the vial socket for retaining a vial 8 within the vial socket. The retaining member further comprises a plurality of retaining latches (40, 44). The retaining member 30 gets narrower near the top (above the retaining latches (40, 44), therefore forming an annular ridge with a smaller inner diameter than the surrounding area.

13. With respect to Claims 21, Haber discloses that the vessel is a cartridge (a “cartridge” may be of any shape) having a neck with a penetrable closure and a cap to retain the closure thereon.

14. Claims 5, 6, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Genese, and further in view of Safabash (US 6,253,804).

15. With respect to Claims 5 and 6, Haber and Genese disclose the device substantially as claimed (see rejection above), and further disclose that the bore of the housing has a first portion, a second portion, and a shoulder disposed therebetween. Haber and Genese, however, do not specifically disclose that the post and hub form a luer connector. Safabash discloses a fluid transfer container system comprising a first container, a second container, and a piston hub 10 disposed therebetween (see figure 1). The containers may be connected to the hub by luer connectors 74 (see Figure 11) to ensure a safe, secure fit (Column 7, Lines 35-39). Luer connectors are extremely well known in the medical fluid transfer art for this very reason. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid transfer system of Haber in view of Genese with the Luer connector of Safabash in order to improve the quality of the seal between containers during medical fluid transfer, thereby ensuring sterility of the fluid.

16. With respect to Claim 14, Haber and Genese disclose the device substantially as claimed, but do not specifically claim that the vessel is a syringe. Safabash discloses a fluid transfer device comprising a syringe that is attached to a piston hub 10. The syringe comprises a neck 34 with a flanged head portion disposed thereon.



Art Unit: 3772

Furthermore, the syringe is positioned such that capable of being pierced by a needle to establish fluid communication. This type of fluid transfer is well established in the art. Therefore, it would have been obvious to one of ordinary skill in the art to replace the first vessel of Haber in view of Genese with a syringe in order to allow for fluid transfer from a different type of container. Additionally, the use of a syringe allows for control (via the piston 40) over the rate at which fluid is dispensed.

17. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Genese and Safabash, and further in view of Haining (US 5,527,306). Haber, Genese, and Safabash disclose the device substantially as claimed (see rejection above), but do not specifically disclose the use of springs as biasing members for the conduit. Haining discloses a vial adapter comprising a spring that surrounds a valve stem and provides an upward force to bias the seat from an open to a closed position (Column 2, Lines 61-67). Springs provide an inexpensive, effective biasing member for improving the functionality of moving parts of a fluid flow device. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Haber, Genese, and Safabash with the resilient biasing spring of Haining in order to cause the device to return to the retracted position quickly and easily, thereby reducing the amount of effort required to operate the device.

18. Claims 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Genese and Safabash, and further in view of Koller (US

2004/0260248). Haber, Genese, and Safabash disclose the device of claim 14 substantially as claimed, but do not disclose that the device further comprises a piston backstop device. Koller discloses a medicinal syringe having a piston stopper means that is shaped and sized to receive a housing, and removably connected to the flange of the syringe. Piston backstops are well established in the art of medical fluid transfer devices because they prevent unintentional withdraw of the piston element from the bore and prevent the device from being reused [0027]. Therefore, it would have been obvious to one of ordinary skill in the art to modify the fluid transfer device of Haber, Genese, and Safabash with the piston stopper of Koller in order to prevent the piston element from being removed from the bore, and to prevent the device from being reused.

19. With respect to Claim 18, Haber discloses that the vessel is a glass container. Glass syringes are also well established in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute a plastic syringe for a glass syringe because the selection of a known material based on its suitability for its intended use does not constitute a patentable improvement over the prior art. See MPEP § 2144.07.

20. With respect to Claims 20 and 24, Haber in view of Genese and Safabash and Koller disclose the device substantially as claimed, but do not specifically disclose that the piston backstop is integrally molded to the vessel. However, the use of a one-piece construction instead of the structure disclosed in the prior art would merely be a matter of obvious engineering choice. See MPEP § 2144.04. Therefore, it would have been

Art Unit: 3772

within the scope of one of ordinary skill in the art at the time of invention to integrate the vessel and the piston backstop in order to simplify the device and prevent reuse of the fluid transfer device. Additionally, the devices of Haber and Genese are fully capable of being used with a plastic vessel. Plastic vessels are extremely common in the art of medical fluid handling.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/  
Examiner, Art Unit 3761

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772